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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SOUTHERN ILLINOIS LABORERS' AND EMPLOYERS HEALTH AND WELFARE FUND; NECA-IBEW WELFARE TRUST FUND; MIDWESTERN TEAMSTERS HEALTH AND WELFARE FUND; THE WELFARE FUND OF TEAMSTERS LOCAL UNION 863; PLUMBERS & PIPEFITTERS LOCAL UNION 630 WELFARE TRUST FUND; CLEVELAND BAKERS AND TEAMSTERS HEALTH AND WELFARE FUND; ELECTRICAL WORKERS BENEFIT TRUST FUND; FIRE & POLICE RETIREE HEALTH CARE FUND, SAN ANTONIO, LABORERS' DISTRICT COUNCIL BUILDING AND CONSTRUCTION HEALTH AND WELFARE FUND; LABORERS' DISTRICT COUNCIL HEAVY AND HIGHWAY UTILITY HEALTH AND WELFARE FUND, and NEW YORK CITY POLICE SERGEANTS BENEVOLENT ASSOCIATION HEALTH & WELFARE FUNDS, individually, and on behalf of all others similarly situated, Plaintiffs, v. PFIZER INC., Defendant.	**No. 08cv5175 (SHS)** **ECF Case** Electronically Filed

DEFENDANT PFIZER INC'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED COMPLAINT

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Defendant Pfizer Inc ("Pfizer") respectfully submits this brief in support of its motion to dismiss Plaintiffs' Second Amended Complaint for lack of standing, pursuant to Federal Rule of Civil Procedure 12(b)(1), failure to state a claim, pursuant to Rule 12(b)(6), and failure to plead their fraud-based claims with specificity, pursuant to Rule 9(b).

PRELIMINARY STATEMENT

Pfizer has twice moved to dismiss Plaintiffs' action for failure to meet federal and state law standards for stating a cognizable claim. Each time, Plaintiffs were granted leave to amend their pleading by the transferor court before the court decided Pfizer's motion. The Second Amended Complaint ("SAC"), their third iteration of their claims, still falls woefully short of the mark: standing, causation, direct injury, and specificity (among other requirements) remain fatal defects in their Complaint, mandating its dismissal with prejudice.

Plaintiffs, eleven unrelated health insurance entities from eight states (collectively, the "Funds"), seek to represent all healthcare benefit plans ("HBPs") across the country that reimbursed some portion of their plan members' cost for prescriptions of Pfizer's cholesterol-lowering medicine, Lipitor®. The Funds do not claim that Lipitor failed to lower cholesterol or that any plan member received a Lipitor prescription other than from a licensed physician exercising his or her own medical judgment. Nor do they claim that any of their members sustained any personal injury as a result of allegedly improper prescriptions for Lipitor. Instead, the Funds challenge the expertise and decisions of the Food and Drug Administration ("FDA"), and prescribing physicians, with conclusory allegations that Pfizer "fraudulently increased demand" for Lipitor, and thereby "improperly inflated" its price, by allegedly misrepresenting, in the FDA-approved Lipitor label and in Pfizer's marketing of Lipitor, the medicine's safety, efficacy, and approved uses. SAC ¶ 5. The Funds assert that they "were damaged because they

were compelled to pay for artificially inflated prices for Lipitor prescriptions." *Id.* ¶ 6. The Funds, however, do not: claim to have received or relied upon any misrepresentation by Pfizer, or identify any physician, patient, or pharmacy benefit manager who did; identify any allegedly unwarranted or improper Lipitor prescription for which they claim to have paid, or a physician who allegedly wrote one; allege that the price of Lipitor decreased after the allegedly concealed information or misrepresentations became known; or allege that they no longer provide, or have ever limited in any way, coverage for Lipitor for their members.

Pfizer categorically denies the Funds' claims that it improperly or unlawfully labeled or promoted Lipitor. But even accepting their allegations as true, the Funds' SAC does not withstand scrutiny under clear and controlling authority affirmatively rejecting claims just like theirs. First, as the Second Circuit recently confirmed, and as numerous courts have held in similar contexts, Plaintiffs' price inflation theory of injury, and related fraud-on-the-market theory of causation, fail as a matter of law. *See McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 222-30 (2d Cir. 2008). Specifically, the SAC does not state a cognizable injury or causal nexus sufficient to satisfy even Article III standing, much less the elements of their RICO and state law claims. Like the Funds here, plaintiffs in *McLaughlin* sought to represent a nationwide RICO class based on claims that defendants' alleged marketing misrepresentations led them to buy a product – there, "light" cigarettes – "in greater quantity than they otherwise would have and at an artificially high price." *Id.* at 220. In its decision reversing class certification, the Second Circuit expressly rejected plaintiffs' theory of injury – that they paid too much for each pack of light cigarettes because defendants' misrepresentations about the relative health risks of the cigarettes had artificially inflated the price for the product – as too speculative as a matter of law. *See id.* at 228-230. The Second Circuit similarly held that plaintiffs could not invoke a fraud-on-the-

market presumption of causation – that is, that defendants' alleged misrepresentations were internalized in the price of light cigarettes, and that, as a result, all light cigarette purchasers were injured by those misrepresentations. *Id.* at 223-224. Because Plaintiffs have alleged the same defective theories of injury and causation here, the SAC should be dismissed in its entirety under *McLaughlin*,[1] which joins a legion of well-reasoned decisions firmly rejecting price inflation injury theories in cases like this. Indeed, courts have dismissed claims nearly identical to Plaintiffs' as "purely speculative," *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007), and "patently absurd." *Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 380 (D.N.J. 2004).

Second, the Funds' claims are preempted because they impermissibly conflict with the FDA's authority and improperly attempt to privately enforce the federal regime governing prescription drug labeling and marketing. Third, the Funds' claims are expressly preempted by the Employee Retirement Income Security Act ("ERISA") because their adjudication would require the Court to interpret, apply, and enforce terms of employee benefit plans. Finally, the Funds' state law claims are fatally defective for multiple additional compelling reasons, spelled out in detail below. In sum, this action remains nothing more than an ill-conceived attempt to second-guess the medical judgment of physicians, displace the regulatory role of the FDA, and reallocate substantial monies to the Funds and other insurers under an entirely speculative and legally untenable theory of causation and injury. Because the SAC fails to state a cognizable claim under federal or state law, it should be dismissed in its entirety, with prejudice.

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[1] The Supreme Court's subsequent decision in *Bridge v. Phoenix Bond & Indem. Co.*, 128 S. Ct. 2131 (2008), does not change this conclusion. There, the Supreme Court held only that RICO does not impose a *first-party* reliance requirement. *Id.* at 2144. The Court otherwise reaffirmed RICO's causation and injury requirements, which the Funds have not satisfied here. Even if *McLaughlin* were subject to modification under *Bridge* to the limited extent it considered reliance by plaintiff to be an *element* of a RICO claim, *McLaughlin's* result, and the portions of the opinion that apply most directly to the instant action, would survive any such modification. Moreover, the Funds' claims for common law fraud and negligent misrepresentation, as well as many of their consumer fraud claims, indisputably require them to plead and prove first-party reliance.

STATEMENT OF FACTS

A. The Funds' Allegations

The Funds bring this putative class action on behalf of a nationwide class and eight statewide classes of HBPs "that paid any portion of the purchase price for Pfizer's cholesterol-lowering drug Lipitor" between January 1, 2002, and the present. SAC ¶ 1. They seek damages and injunctive relief under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO") and for consumer fraud and common law claims under the laws of the Funds' home states of Illinois, New Jersey, Florida, Ohio, Indiana, Texas, Pennsylvania, and New York.

The SAC alleges that Pfizer wrongfully increased the number of Lipitor prescriptions written by doctors and inflated Lipitor's price by:

(1) promoting Lipitor to regulate cholesterol in patients who are at "moderate risk" for developing coronary heart disease ("CHD") under the evolving treatment guidelines developed by the National Cholesterol Education Program (the "NCEP Guidelines"),[2] a use the Funds allege is "off-label" (*see, e.g.*, SAC ¶¶ 3, 5, 49, 111);

(2) failing to include in the Lipitor label and Lipitor promotional materials statements about certain risks and side effects that the Funds – but not the FDA – claim to be warranted based on certain newspaper and journal articles and case reports cited by the Funds (*see, e.g., id.* ¶¶ 2, 4, 5, 25, 30, 59-62, 82-88, 95, 97, 100, 101, 226, 237-42, 252-57, 264);

(3) failing to disclose what the Funds – but not the FDA – assert is an absence of scientific support for Lipitor's FDA-approved indication for cardiovascular benefits in women and people over 65 (*see, e.g., id.* ¶¶ 2, 4, 25, 102-04, 226, 238); and

(4) making unidentified misleading claims of comparative superiority over other brand name and generic statins (cholesterol-lowering drugs). *See, e.g., id.* ¶¶ 2, 30, 95, 111, 226, 239, 252-53.

The Funds do not allege that Pfizer made any false or misleading statement directly to them (and Pfizer categorically denies that it made any such statements to any one). Rather, they

[2] *See* NCEP, *Information About the Update of the Adult Treatment Panel III Guidelines, available at* http://www.nhlbi.nih.gov/guidelines/cholesterol/upd-info_prof.htm (last visited July 20, 2008).

assert in general terms that Pfizer and its proxies omitted or misrepresented information about Lipitor in its FDA-approved label and in advertisements and presentations targeted to pharmacy benefit managers (or "PBMs"), physicians, and consumers, and that the number and price of Lipitor prescriptions increased as a result. *See, e.g.*, SAC ¶¶ 114-49. But after over twenty-six months of litigation, including access to every Lipitor advertisement and promotional piece since 2001, and two motions to dismiss highlighting their numerous pleading deficiencies, the Funds still do not identify a single PBM, physician, or consumer who was allegedly misled or influenced by an improper off-label promotional effort or a statement by Pfizer that is inconsistent with Lipitor's FDA-approved label, much less a single Lipitor prescription written and paid for as a result of any such effort or statement.

B. Regulatory Background

Congress has vested the FDA with plenary authority over prescription drug approval, labeling, and marketing.[3] The FDA will approve a "new drug application" ("NDA") only "after it determines that the drug meets the statutory standards for safety and effectiveness . . . and labeling." 21 C.F.R. § 314.105(c) (2008). An approved label "reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

Lipitor was approved by the FDA in 1996, and since that time, has always been approved for use in men, women, and the elderly both to decrease total LDL cholesterol levels and to

[3] *See* Federal Food, Drug and Cosmetic Act of 1938 ("FDCA"), Ch. 675 § 1, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.); *see also, e.g.*, 21 U.S.C. § 355 and 21 C.F.R. § 314.125(b)(6) (2008) (addressing prescription drug approval and labeling); 21 U.S.C. §§ 321(n), 331(a), 352(n) and 21 C.F.R. §§ 202.1, 314.81(b)(3)(i) (2008) (addressing prescription drug advertising and marketing).

increase HDL cholesterol levels. *See* Ex. 1, 1996 Lipitor Label at 1.[4] On July 30, 2004, the FDA expressly approved a new indication for Lipitor: the prevention of cardiovascular disease "in adult patients without clinically evident coronary heart disease, but with multiple risk factors." Ex. 2, July 2004 Lipitor Label at 9. The Funds do not allege that Pfizer withheld any information from the FDA, or that the FDA has required Pfizer to change the safety information in its label in any way based on the clinical studies and publicly available articles and case reports that the Funds allege support their assertions about purportedly undisclosed, or inadequately disclosed, side effects or risks of statins. *See* SAC ¶¶ 59-62, 100-01. Indeed, as Lipitor's FDA-approved label confirms, the FDA has reviewed relevant clinical studies as part of the NDA process, and has concluded that the medicine is safe and effective for the reduction of cholesterol and the prevention of heart disease in adults determined to be at risk for CHD, including women and the elderly. The Funds' challenges to the Lipitor label and their attacks on Pfizer's marketing in conformance with the label directly contradict the FDA's own findings.

STANDARDS FOR DISMISSAL

On a motion under Rule 12(b)(1), the plaintiff invoking federal subject matter jurisdiction bears the burden of establishing standing. *See Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). "'[T]he irreducible constitutional minimum of standing'" requires "'an ''injury-in-fact,"-an invasion of a legally protected interest which is (a) *concrete and particularized*, and (b) *actual or imminent, not conjectural or hypothetical*,'" and "'*a causal connection between the*

[4] On a motion to dismiss, a court may consider attached documents that are referred to in the complaint and are central to the claims. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). A court may also take judicial notice of public records, such as an FDA-approved drug label. *See Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002). Importantly, what Plaintiffs refer to as the Lipitor "label" (*see* SAC ¶¶ 82-85) is the FDA-approved *patient* information insert, not the full label or prescribing information. *See* Ex. 3, Lipitor Patient Information Insert. The insert is written in lay terms and does not contain all of the information that is included for physicians in the label. *See* Ex. 4, November 2007 (current) Lipitor Label.

injury and the conduct complained of.'" *Port Washington Teachers' Ass'n v. Bd. of Educ.*, 478 F.3d 494, 498 (2d Cir. 2007) (emphasis added) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Where a plaintiff cannot satisfy these requirements, the court must dismiss. *See Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319 (5th Cir. 2002) ("[W]e must decide standing first, because it determines the court's fundamental power even to hear the suit.").

A Rule 12(b)(6) motion should be granted where a plaintiff is unable to delineate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 1965; *accord ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 & n.2 (2d Cir. 2007). A district court "'retain[s] the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.'" *Twombly*, 127 S. Ct. at 1967 (citation omitted). In particular, because of the "'almost inevitable stigmatizing effect'" of RICO claims, "'courts should strive to flush out frivolous RICO allegations at an early stage of the litigation.'" *Katzman v. Victoria's Secret Catalogue*, 167 F.R.D. 649, 655 (S.D.N.Y. 1996) (citation omitted), *aff'd*, 113 F.3d 1229 (2d Cir. 1997).

ARGUMENT

I. THE FUNDS DO NOT HAVE STANDING UNDER ARTICLE III AND CANNOT OTHERWISE MAINTAIN THEIR RICO OR STATE LAW CLAIMS BECAUSE THEY HAVE NOT ALLEGED A COGNIZABLE INJURY OR CAUSAL NEXUS

Because the SAC alleges only hypothetical, indirect injury – price inflation – it should be dismissed for both lack of constitutional standing and failure to adequately plead two essential elements of the Funds' RICO and state law claims: injury and causation.

A. The Funds' Price Inflation Theory of Injury Does Not Satisfy Article III

The SAC fails as a threshold matter to establish Article III standing by pleading a "concrete injury that can fairly be traced" to Pfizer's alleged conduct. *Jaghory v. N.Y. Dep't of*

Educ., 131 F.3d 326, 329-30 (2d Cir. 1997). The Funds do not allege that a single physician prescribed Lipitor to any Fund member as a result of purportedly wrongful promotion by Pfizer, that Lipitor did not reduce the cholesterol of any member, or that any member sustained any negative health effect as a result of taking Lipitor.[5] Indeed, the Funds have never identified a single improperly prescribed, harmful, or ineffective Lipitor prescription for which they have paid. Instead, the Funds seek to pursue their claims based solely on their speculation that they paid some undisclosed amount more for Lipitor than they should have. *See, e.g.*, SAC ¶¶ 5, 6, 178.[6] In their briefing and at hearings on discovery motions, the Funds have repeatedly emphasized that their SAC is premised entirely on a price inflation theory of injury.[7] It is well settled, however, that the mere expenditure of money, even at an allegedly "inflated" price, is not, on its own, a cognizable injury or compensable loss. Rather, the economic injury must be tied directly to the defendant's alleged misconduct. *See generally Rivera*, 283 F.3d at 319-21; *see also Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342-47 (2005) (allegation that deception caused inflated price does not satisfy burden to plead injury caused by deception). Here, the Funds attempt to plead a causal nexus by alleging that a "fraud on the market," in the form of alleged misrepresentations or omissions about Lipitor, created an artificially high price for the medicine. *See, e.g.*, SAC ¶¶ 5-6; s*ee also In re Rezulin Prods. Liab. Litig.*, 524 F. Supp. 2d 436, 441 (S.D.N.Y. 2007) ("[Plaintiffs] argue that they are entitled to recover because defendants

[5] Moreover, the Funds cannot "bypass the elements of subrogation actions" by bringing a "direct" lawsuit. *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 821 (7th Cir. 1999); *see also Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 244 (2d Cir. 1999).

[6] *See also* SAC ¶¶ 8-18, 71, 95-98, 105, 203, 216, 218, 220, 222, 227, 231-33, 240-42, 246-48, 252-53, 255, 259-61, 265, 270-71, 274, 276, 283, 290-91, 295, 297, 301, 305-06, 309, 312.

[7] *See, e.g.*, Pls.' Mem. of Law in Support of Mot. to Modify Discovery [N.D. Ill. D.E. 131] at 2 ("Put simply, the SAC alleges that Pfizer's false and misleading promotion of Lipitor resulted in Lipitor's price being higher than it would have been without such promotion."); *see also* Pls.' Am. Objections to Magistrate Brown's Order Dated Nov. 14, 2007 [N.D. Ill. D.E. 173] at 1-2.

misled patients and the medical community concerning the safety and efficacy of Rezulin in consequence of which, they claim, [they were] called upon to reimburse for prescriptions that otherwise would not have been written at prices that otherwise could not have been charged. This, as defendants maintain, is a 'quintessential fraud-on-the-market' theory.").

Fraud on the market is a theory of establishing economic loss and causation in *securities cases* by pleading and proving that a plaintiff purchased securities at "prices that had been artificially affected by an issuer's misrepresentations and omissions." *Kaufman v. i-Stat Corp.*, 754 A.2d 1188, 1189 (N.J. 2000); *accord Sec. Investor Prot. Corp. v. BDO Seidman, LLP*, 222 F.3d 63, 72 (2d Cir. 2000); *see also In re Rezulin*, 524 F. Supp. 2d at 441 ("The fraud-on-the market theory is a creature of federal securities laws."). The Second Circuit and many others have flatly rejected efforts to apply this theory outside the context of securities fraud. *See McLaughlin*, 522 F.3d at 224 (refusing to apply fraud-on-the-market presumption to light cigarette RICO claims, explaining that, in contrast to the "efficient market . . . in securities traded on the New York Stock Exchange[;] the market for consumer goods . . . is anything but efficient"); *Sec. Investor Prot. Corp.*, 222 F.3d at 73 ("[F]ederal courts repeatedly have refused to apply the fraud on the market theory to state common law cases . . . .").[8]

The Second Circuit further addressed, and rejected as a matter of law, the same theory of price inflation injury that the Funds allege here. The court determined that whether such injury were to be measured as: (a) "the difference between the price plaintiffs paid for [the product] as represented by defendants and the (presumably lower) price they would have paid (but for defendants' misrepresentation) had they known the truth," *McLaughlin*, 522 F.3d at 228, or (b) in

[8] *Accord Summit Props. Inc. v. Hoechst Celanese Corp.*, 214 F.3d 556, 561 (5th Cir. 2000); *see also Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1364 (11th Cir. 2002); *Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1369 n.39 (11th Cir. 1997); *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 403-04 (6th Cir. 1997).

terms of "the amount by which defendants would have had to reduce their prices to account for the concomitant reduced demand" for the product after the truth were disclosed, *id.* at 230, the theory of injury is too speculative and fails *as a matter of law. See id.* at 229 ("plaintiffs' [loss of value] theory is pure speculation" and "fails at its inception"); *id.* at 230 ("[A] court considering plaintiffs' price impact model would have to engage in a series of speculative calculations to ascertain whether, and in what amount, plaintiffs suffered a loss."; "[T]heir price impact theory, like their loss of value theory, fails as a matter of law."). As the court explained, the impermissibly speculative nature of plaintiffs' price inflation injury derived in part from the possibility that any alleged inflation "could have resulted from factors unrelated to the . . . alleged acts of fraud," such as any of the many "variables [that] bear on cigarette price." *Id.* The Second Circuit's analysis applies directly to, and bars, the Funds' claims here.

Indeed, numerous courts applying reasoning like the Second Circuit's in *McLaughlin* have held that cases involving prescription drug marketing are particularly ill-suited for fraud-on-the-market and price inflation theories of causation and injury. *See In re Rezulin,* 524 F. Supp. 2d at 441 (rejecting theory in action seeking recovery for state's payments for Rezulin); *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) (rejecting "plaintiffs' claim that they have been injured by 'price inflation' [as a result of Pfizer's marketing of Lipitor] because, in the context of the pharmaceutical market, such damages are purely speculative"); *Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 369 (D.N.J. 2004) (dismissing claims that "Defendants' 'uniform failure to disclose known cardiovascular risks associated with Celebrex and Vioxx caused consumers to pay artificially inflated prices for them'") (citation omitted); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 172 (D.D.C. 2003) (dismissing action alleging that "over-promotion of OxyContin inflated the price of the drug so that all class

members 'paid a higher price for [it]'"); *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007) (holding that plaintiff's theory "that the price charged for Vioxx was higher than it should have been as a result of defendant's fraudulent marketing campaign . . . must fail"); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 176, 178-79 (N.J. Super. Ct. App. Div. 2003) (affirming dismissal of action alleging that marketing drove price for allergy medicine Claritin "up to artificially high levels").

Significantly, in *Prohias*, plaintiff health benefit funds and individuals alleged, as the Funds do here, that Pfizer improperly promoted Lipitor for the prevention of heart disease among women and the elderly, and that "[s]uch misleading advertising . . . create[d] artificial demand for Lipitor and an artificial increase in Lipitor's price, thus causing economic injury to Lipitor purchasers." 485 F. Supp. 2d at 1332. Plaintiffs there, as here, "contend[ed] that they [were] injured within the meaning of the consumer fraud statutes of the respective states because they paid a higher price for Lipitor than the market would have borne if not for Pfizer's advertising scheme – specifically, they allege[d] 'price inflation' damages." *Id.* at 1336. In addition to finding certain claims of improper marketing preempted (*see infra* Part II), the court held that

> **in the context of a market for a pharmaceutical drug, such [price inflation] damages are too speculative to constitute an injury-in-fact under Article III**. In particular, proof of any such "price inflation" injury would depend on evidence that the pharmaceutical market is "efficient" such that information about Lipitor's efficacy results in changes in its price.

Id. (emphasis added). Following *Heindel*, the court recognized that unlike securities, prescription drugs are not constantly re-priced based on the current mix of information in the market, and that there is no clear correlation between the price of and demand for a drug. *Id.* at 1337 ("[D]rug prices (unlike stock prices which are necessarily set by the price at which buyers are willing to buy, or sellers willing to sell) are fixed by the product's manufacturer."); *Heindel*, 381 F. Supp. 2d at 380 ("In [the pharmaceutical] context . . . [a fraud-on-the-market or price

inflation theory] is patently absurd. . . . [T]here is no prescription drug 'market' . . . .").

Moreover, as the court observed in *Prohias*, any showing of damages

> under the "price inflation" theory (assuming the price did incorporate information about Lipitor's benefits), would require evidence of the hypothetical price at which Lipitor would sell if not for the allegedly misleading advertisements. **Determination of such *hypothetical* price, even with expert proof, is too speculative to be the premise of an "actual injury" under Article III.**

485 F. Supp. 2d at 1337 (emphasis added). Here, as in *Prohias*, "it would be too speculative for purposes of Article III to reach any conclusions as to the effect of Pfizer's advertising on the market price for Lipitor." *Prohias*, 485 F. Supp. 2d at 1337; *cf. McLaughlin*, 522 F.3d at 229.

Other courts have similarly held that price inflation theories like the Funds', based on alleged misrepresentations about a medicine's safety or efficacy, do not state a cognizable injury under Article III. In *Williams*, for example, plaintiffs claimed that "'Defendants *could not have charged such a high price for* OxyContin had it been known that it actually, routinely failed to provide effective pain relief for twelve hours, and that it presented the same abuse and addiction risks as morphine and other opioids.'" 297 F. Supp. 2d at 175 (emphasis added) (citation omitted). Noting that "[s]tanding requires 'individualized proof' of both the fact and the extent of injury," the court held that plaintiffs' complaint "fail[ed] in two respects": first, "[w]hile it assert[ed] that defendants engaged in false and misleading advertising, it [did] not plead that these [plaintiffs] were in any way deceived – or even saw – any of that advertising"; and second, "[i]t also fail[ed] to allege any particularized and specific injury-in-fact suffered by these plaintiffs," because plaintiffs did not challenge the drug's effectiveness as to them. *Id.* at 177 (citation omitted). The Funds' claims here are just as, if not more, deficient.

Similarly, in *Rivera v. Wyeth-Ayerst Laboratories*, the Fifth Circuit reversed the "fatally flawed" certification of a nationwide class of drug purchasers and their insurance companies, and ordered that the action be dismissed, because it "[did] not even present a justiciable case or

controversy under Article III." 283 F.3d 315, 318 (5th Cir. 2002). Plaintiff Rivera's "claim to injury [ran] something like this: Wyeth sold Duract [a prescription pain medication]; Rivera purchased and used Duract; Wyeth did not list enough warnings on Duract, and/or Duract was defective; other patients [but not Rivera] were injured by Duract; Rivera would like her money back." *Id.* at 319. The court held that plaintiffs had failed to "plead facts essential to establish causation" because they did not assert any facts that could show that "had Wyeth acted 'lawfully' (produced a safer drug or provided more extensive warnings), the physicians would not have prescribed – *and* the plaintiffs would not have purchased – Duract." *Id.* at 321. The court explained: "To find causation, we would have to infer the absurd – for example, that an extra warning, though inapplicable to Rivera, might have scared her and her doctor from Duract. Such reasoning is too speculative to establish Article III standing." *Id.*; *accord In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 484 F. Supp. 2d 973, 984 (D. Minn. 2007) (dismissing HBPs' claims for damages, including the purchase price of allegedly defective pacemakers used by their members, as "too speculative" under Article III because they depended on "the independent choices of the doctors who recommend[ed] the [pacemakers] to their patients and on the patients who decide[d] to receive the devices"), *reconsideration granted in part on other grounds*, 2007 WL 2028137 (D. Minn. May 9, 2007).

The Funds' claims rely on the same speculative reasoning that was rejected in *Rivera* and *Guidant* – that absent Pfizer's alleged misrepresentations, physicians would not have written prescriptions for the purportedly off-label use of Lipitor,[9] or would not have prescribed Lipitor to

[9] The FDA recognizes the independent judgment of doctors and permits them to prescribe medicines for "any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA." *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000); *see also Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001) (prescribing off-label is an "accepted and necessary" part of medicine); SAC ¶ 37.

the Funds' members at all, and PBMs would not have included Lipitor on the Funds' prescription drug formularies, or would have limited its placement in some way. *See, e.g.*, SAC ¶¶ 98, 104-05, 125. The SAC does not "adduce any facts supporting" such a causal nexus with regard to any of the Funds. *Rivera*, 283 F.3d at 321. The Funds do not identify a single physician or PBM that was allegedly misled by Pfizer. Nor do the Funds plead that they no longer cover Lipitor prescriptions for their members, or that they have made any changes to their reimbursement policy for Lipitor, even though, like plaintiffs in *Prohias*, "they are purportedly now aware of": (i) "the 'truth' regarding [Lipitor's] alleged lack of coronary benefits," 485 F. Supp. 2d at 1335; (ii) the risk and efficacy information that they allege should have been included in Lipitor's label; (iii) Pfizer's alleged off-label and otherwise improper marketing; and (iv) the allegedly "inflated price" of Lipitor. As the court in *Prohias* concluded, "[t]aking the allegations in the complaint in the light most favorable to these plaintiffs, who continue to pay for Lipitor with knowledge as to its alleged limitations, I cannot come up with any theory upon which they are actually injured or aggrieved." *Id.* at 1336. Likewise, here, despite their claims that Pfizer's alleged misconduct inflated Lipitor's price, the Funds do not allege in their SAC – filed nearly eighteen months after they first alleged such misconduct – any decrease in the demand for or price of Lipitor since the "truth" has been known. *See McLaughlin*, 522 F.3d at 227 ("Given the lack of an appreciable drop in the demand or price of light cigarettes after the truth about Lights was revealed . . . , plaintiffs' argument that defendants' misrepresentation caused the market to shift and the price of Lights to be inflated fails as a matter of law.").

B. The Funds Do Not Have RICO Standing

Plaintiffs' price inflation theory of injury is also fatally deficient for purposes of RICO standing, which requires each Fund to plead that it was "injured in [its] business or property *by reason of* a violation of section 1962" of the statute. 18 U.S.C. § 1964(c) (emphasis added); *see*

also McLaughlin, 522 F.3d at 227 ("A plaintiff asserting a claim under 18 U.S.C. § 1964(c) must allege *actual*, quantifiable injury."). It is also well established that "a cause of action does not accrue under RICO until the amount of damages becomes *clear and definite*." *First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 768 (2d Cir. 1994) (emphasis added); *see also id.* (plaintiff did not have RICO standing where the "actual amount of its injury was indefinite and unprovable"); *Evans v. City of Chicago*, 434 F.3d 916, 932 (7th Cir. 2006) (RICO injury must be "'concrete and actual,' as opposed to speculative and amorphous") (citations omitted).

Recent Supreme Court and Second Circuit decisions confirm that the Funds' RICO claims fail as a matter of law because they have not alleged that Pfizer's purported predicate RICO violations – mail and wire fraud – were both a "but for" cause *and* the proximate cause of their claimed injury. *See Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457-62 (2006) (citing *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992)); *accord McLaughlin*, 522 F.3d at 222-23; *BCCI Holdings (Luxembourg), Societe Anonyme v. Pharaon*, 43 F. Supp. 2d 359, 365 (S.D.N.Y. 1999) (Stein, J.). In *Anza*, the Supreme Court confirmed that the central component of the proximate cause analysis is the presence of a *direct* injury. *See Anza*, 547 U.S. at 460 ("There is no need to broaden the universe of actionable harms to permit RICO suits by parties who have been injured only indirectly."). As the Second Circuit has explained, a direct injury "is a key element for establishing proximate causation, independent of and in addition to other traditional elements of proximate cause." *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 235-36 (2d Cir. 1999) ("*Laborers Local 17*"); *see also First Nationwide Bank*, 27 F.3d at 770 ("The key reasons for requiring direct causation include avoiding unworkable difficulties in ascertaining what amount of the plaintiff's injury was caused by the defendant's wrongful action as opposed to other external factors, and in apportioning

damages between causes."). To satisfy this requirement, a plaintiff must plead facts establishing a direct relationship between the predicate RICO violation and a plaintiff's purported damages. *See Anza*, 547 U.S. at 457-58. "'[W]hen factors other than the defendant's fraud are an intervening direct cause of a plaintiff's injury, that same injury cannot be said to have occurred by reason of the defendant's actions.'" *McLaughlin*, 522 F.3d at 226 (quoting *First Nationwide Bank*, 27 F.3d at 769); *accord Mendelovitz v. Vosicky*, 40 F.3d 182, 185 (7th Cir. 1994) (where alleged damages "require actions and decisions by third parties before coming into being," there is no direct injury); *Pharaon*, 43 F. Supp. 2d at 365-66.

Here, the alleged "racketeering acts" are the use of the U.S. mail and interstate wire facilities in order to "induce[] physicians to prescribe Lipitor to patients who will not benefit from the drug." SAC ¶ 203. As a threshold matter, the Funds have failed to meet the requirement that they plead those predicate acts with specificity by: "(1) specify[ing] the statements that the plaintiff contends were fraudulent, (2) identify[ing] the speaker, (3) stat[ing] where and when the statements were made, and (4) explain[ing] why the statements were fraudulent." *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993).[10] "To link their own injuries to the alleged RICO enterprise, plaintiffs must allege what happened to them," as opposed to a putative class. *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 659 (3d Cir. 1998) (affirming dismissal of RICO class action for failure to plead with specificity).

The Funds do not identify a single fraudulent mail or wire transmission allegedly made to any Fund member, prescribing physician, or PBM, much less any of the Funds themselves – let alone allege a pattern of such statements – with the specificity required by Rule 9(b). This alone

[10] *Accord Globe Wholesale Tobacco Distribs. Inc. v. Worldwide Wholesale Trading Inc.*, No. 06 Civ. 2865, 2007 WL 2826630, at *2 (S.D.N.Y. Sept. 28, 2007).

warrants dismissal.[11] *See First Capital Asset Mgmt., Inc. v. Brickelbush, Inc.*, 150 F. Supp. 2d 624, 632 (S.D.N.Y. 2001) (dismissing RICO claims because of a "dearth of facts" supporting the alleged RICO predicate acts), *aff'd sub nom. First Capital Asset Mgmt., Inc. v. Satinwood, Inc.*, 385 F.3d 159 (2d Cir. 2004). Moreover, even disregarding the Funds' failure to plead with specificity, any hypothetical price inflation or other injury to the Funds resulting from the alleged "racketeering" necessarily "require[d] actions and decisions by" numerous third parties – including doctors in prescribing Lipitor and PBMs in including Lipitor on the Funds' formularies – "before coming into being." *Mendelovitz*, 40 F.3d at 185. Such damages are too remote as a matter of law to establish RICO standing. As the Second Circuit observed in *Laborers Local 17*, "the direct injury test can be seen as wisely limiting standing to sue to those situations where the chain of causation leading to damages is not complicated by the intervening agency of third parties." 191 F.3d at 240. Indeed, courts have recognized that the necessary presence of a prescribing doctor breaks the causal nexus between an alleged misrepresentation in a marketing campaign and a patient's purchase and use of a drug, since doctors, as "learned intermediar[ies]," exercise independent judgment "whether or not to prescribe a particular medication." *New Jersey Citizen Action*, 842 A.2d at 177-78 ("[W]ithin a highly regulated industry in which the ultimate consumer is not in fact free to act on claims made in advertising . . . , the relationship between words used in the advertising and purchase of the product is at best an attenuated one."); *accord Heindel*, 381 F. Supp. 2d at 384.

[11] Several recent "off-label" marketing cases confirm that the Funds have not properly pled *any* of their fraud-based claims. *See, e.g., United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, No. 03 C 8239, 2007 WL 2091185, at *4 (N.D. Ill. July 20, 2007) (dismissing action alleging defendant promoted its medicines for off-label uses where plaintiff failed to allege, pursuant to Rule 9(b), "which sales representatives made the statements, when they made them, to which doctors they made them or how they communicated them"); *accord United States ex rel. McDermott v. Genentech, Inc.*, No. 05-147, 2006 WL 3741920, at *10-13 (D. Me. Dec. 14, 2006); *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV570, 2006 WL 1064127, at *6-11 (E.D. Mo. Apr. 21, 2006).

The causal chain is further attenuated by the decisions of the PBMs that, as several courts have observed, rely on independent committees of medical experts to "review[] each drug for safety, efficacy, and cost" and determine whether and how to include it on a HBP's formulary. *In re Rezulin Prods. Liab. Litig.*, 390 F. Supp. 2d 319, 326-27 (S.D.N.Y. 2005); *see also Int'l Union of Operating Eng'rs*, 929 A.2d at 1080-81, 1087 (describing range of drug-specific decisions made by PBMs and their specialized committees). The uncertainty and speculation created by the necessary intermediary decisions and actions of doctors, patients, and PBMs preclude a finding of direct injury to the Funds. *See Anza*, 547 U.S. at 458 (dismissing claim that alleged tax evasion by plaintiffs' competitor enabled it to sell at lower prices because competitor "could have lowered its prices for any number of reasons unconnected to [its] asserted pattern of fraud"); *First Nationwide Bank*, 27 F.3d at 772 (affirming dismissal of RICO action by mortgage lender against brokers and borrowers where plaintiff "[did] not adequately plead facts which, if proven, would show that its loss was caused by [defendants'] alleged misstatements as opposed to intervening events").[12] Furthermore, the Funds' allegations that Pfizer misrepresented Lipitor's safety, efficacy, and approved uses suggest the existence of parties who may actually have direct injury claims and who would be better suited to "vindicate the law . . . without any of the problems attendant upon suits by plaintiffs injured more remotely." *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 269-70 (1992); *see also Laborers Local 17*, 191 F.3d at 241 (availability of actions to individual smokers weighed heavily against RICO standing for HBPs). Here, those parties include both Lipitor patients and the FDA.

[12] Indeed, numerous courts have dismissed comparable claims by HBPs seeking damages based on the cost of providing coverage to members, for failure to establish a direct injury. *See, e.g., Laborers Local 17*, 191 F.3d at 239-41, 244 (directing dismissal of RICO action against tobacco companies because alleged injuries were too remote as a matter of law); *see also Perry v. Am. Tobacco Co.*, 324 F.3d 845, 848 (6th Cir. 2003); *Serv. Employees Int'l Union Health & Welfare Fund v. Philip Morris Inc.*, 249 F.3d 1068, 1074 (D.C. Cir. 2001); *Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 825-26 (7th Cir. 1999).

The SAC further fails under the Supreme Court's analysis in *Anza* because the Funds' price inflation theory of damages would force a fact-finder to engage in exactly the kind of speculation that the proximate causation standard is intended to avoid. *See Anza*, 547 U.S. at 459-61. In *Anza*, for example, where plaintiff Ideal alleged that competitor National's failure to charge its customers state sales tax allowed National to increase its market share at Ideal's expense (*id.* at 454), the Court observed that any damages proceeding would be too speculative:

> A court considering the claim would need to begin by calculating the portion of National's price drop attributable to the alleged pattern of racketeering activity. It next would have to calculate the portion of Ideal's lost sales attributable to the relevant part of the price drop. The element of proximate causation recognized in *Holmes* is meant to prevent these types of intricate, uncertain inquiries from overrunning RICO litigation.

Id. at 459-60. The Funds' price inflation injury theory would require the same type of "intricate, uncertain inquiries" – including about the *hypothetical* price at which Lipitor would sell if not for Pfizer's alleged misrepresentations – that the Supreme Court has found impermissible under RICO. *See McLaughlin*, 522 F.3d at 230 ("[Plaintiffs'] price impact model exemplifies the kind of vague inquiry into damages that the Supreme Court forbade in *Anza*."); *Laborers Local 17*, 191 F.3d at 240 (directing dismissal where HBPs' RICO action would result in "the sheerest sort of speculation" to determine damages); *Longmont United Hosp. v. St. Barnabas Corp.*, No. 06-2802, 2007 WL 1850881, at *8 (D.N.J. June 26, 2007) (dismissing RICO claim where calculating damages "would be arduous [and] complex and would lead to speculation").

Furthermore, for the reasons set forth above, the Funds' allegations of class-wide (as opposed to Plaintiff-specific) "overpayment" for Lipitor, based on their speculative theory of price inflation injury (*see, e.g.*, SAC ¶ 218, 220), do not satisfy the requirement of "*clear and definite*" damages. *First Nationwide Bank*, 27 F.3d at 768; *see also Goldfine v. Sichenzia*, 118 F. Supp. 2d 392, 399 (S.D.N.Y. 2000). Here, as in *McLaughlin*, the only potentially "acceptable

measure of injury" under RICO is "out-of-pocket damages," on a plaintiff-by-plaintiff basis. *McLaughlin*, 522 F.3d at 227; *Brown v. Protective Life Ins. Co.*, 353 F.3d 405, 407 (5th Cir. 2003) (named plaintiffs must allege concrete injury that is specific to themselves). Like plaintiffs in *McLaughlin*, the Funds have intentionally avoided alleging actual out-of-pocket injury, even though they would have such information at their disposal if it existed. *See McLaughlin*, 522 F.3d at 228. They have not alleged that any prescription for which any of them paid was ineffective for or harmful to the member to whom it was prescribed,[13] much less tied any such prescription to a statement by Pfizer. Instead, they rely entirely on conclusory claims that the Lipitor they paid for was worth less than what they paid. The *McLaughlin* court expressly rejected that theory of injury under RICO because it required speculation and "would lead to an impermissible fluid recovery." *Id.* at 227; *see also In re Bridgestone/Firestone, Inc. Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1017 & n.1 (7th Cir. 2002) (the law does not support claims for damages by "uninjured buyers . . . on the theory that the risk of failure made each [product] less valuable"); *accord Rivera*, 283 F.3d at 320.[14]

C. The Funds' Failure to Plead Injury, Causation, or Reliance Requires Dismissal of Their State Law Claims

Like their RICO claims, the Funds' state law claims fail because they have not alleged injury or causation, much less the reliance required for fraud and negligent misrepresentation.

1. Consumer Protection Claims

A number of courts have squarely rejected attempts to satisfy the causation and injury elements of state consumer protection claims through a fraud-on-the-market or price inflation

[13] Moreover, such allegations could proceed, if at all, only through subrogation. *See supra* n. 5.

[14] *See also Maio v. Aetna, Inc.*, 221 F.3d 472, 484, 499-500 (3d Cir. 2000) (claims that marketing scheme induced plaintiffs to "pa[y] too much in premiums," without allegations that health care *actually received* was inadequate, did not state RICO injury); *Impress Commc'ns v. Unumprovident Corp.*, 335 F. Supp. 2d 1053, 1065 (C.D. Cal. 2003) ("premium payments alone do not constitute injury" under RICO).

theory. In *Oliveira v. Amoco Oil Co.*, 776 N.E.2d 151 (Ill. 2002), for example, the Illinois Supreme Court upheld the trial court's dismissal of a putative nationwide class action under the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA") that was based on allegations strikingly similar to those the Funds assert here. 776 N.E.2d at 154. Plaintiff alleged that: (i) Amoco falsely advertised "that the use of its premium gasolines would improve engine performance and benefit the environment"; (ii) the "advertisements increased consumer demand for the premium gasolines"; and (iii) as a result, Amoco was able to "'command an inflated . . . price for its premium gasolines,' thereby proximately causing actual damage to all purchasers." *Id.* The court held that plaintiff's "market theory" failed to adequately plead proximate causation – that is, that plaintiff was deceived by defendant's advertisements – under the ICFA. *Id.* at 155. It noted that the theory would impermissibly extend claims to both "purchasers of defendant's premium gasolines who saw the ads but never believed them, *i.e.*, those who 'knew the truth'" and "purchasers of defendant's premium gasolines who never saw the ads and, thus, were 'not deceived.'" *Id.* at 164; *accord Avery v. State Farm Mut. Auto. Ins. Co.*, 835 N.E.2d 801, 861 (Ill. 2005) (affirming rejection of market theory of causation under the ICFA).

The Pennsylvania Supreme Court similarly rejected a fraud-on-the-market theory in a gasoline consumer action under Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"). *See Weinberg v. Sun Co.*, 777 A.2d 442, 445-46 (Pa. 2001) (allegations and proof that plaintiffs had "paid more for the gasoline than [they] would have paid" absent defendant's false advertising were insufficient to satisfy the UTPCPL's "ascertainable loss" and reliance elements); *accord Heindel*, 381 F. Supp. 2d at 381 ("Plaintiffs cannot use the fraud on the market theory to circumvent the reliance element of the UTPCPL."). And, as noted *supra*, in two prescription drug marketing actions similar to this one, New Jersey's courts found it "plain

that the theories [of fraud-on-the-market or price inflation] have no place as a part of the proofs required of plaintiffs in the [New Jersey Consumer Fraud Act ("NJCFA")] context." *New Jersey Citizen Action*, 842 A.2d at 178; *accord Int'l Union of Operating Eng'rs*, 929 A.2d 1087-88.

These authorities not only mandate dismissal of the Illinois, Pennsylvania, and New Jersey Funds' consumer protection claims, but also, together with the RICO authorities cited above, direct dismissal of each of the other Funds' statutory claims, all of which similarly require allegations of an injury caused by a deceptive act by Pfizer.[15] *See, e.g.*, *Perry*, 324 F.3d at 850 (dismissing negligence, consumer fraud, and unjust enrichment claims, together with RICO claims, nothing that "remoteness principles are not limited to cases involving the RICO statute").

2. Fraud and Negligent Misrepresentation Claims

The Funds' fraud and negligent misrepresentation claims are subject to dismissal not only for failure to plead fraud with specificity (*see supra* Part I.B) and failure to allege a cognizable injury, as established in detail above, but also because the Funds have not alleged an injury based on their own reasonable or justifiable *reliance*, an additional essential element of each of those claims.[16] To plead reliance, the Funds must allege that their actions were *induced* by Pfizer's statements. *See, e.g.*, *Sec. Investor Prot. Corp. v. BDO Seidman, LLP*, 49 F. Supp. 2d 644, 655 (S.D.N.Y. 1999) (to plead fraud, "a plaintiff must allege the 'misrepresentation of a material fact made with scienter that induces reliance to the detriment of the party to whom the misrepresentation is directed'") (citation omitted), *aff'd in relevant part*, 222 F.3d 63 (2d Cir.

[15] *See, e.g.*, Florida: *Berenguer v. Warner-Lambert Co.*, No. 02-05242, 2003 WL 24299241, at *2 (Fla. Cir. Ct. July 31, 2003); Indiana: *Captain & Co. v. Stenberg*, 505 N.E.2d 88, 98 (Ind. Ct. App. 1987); New York: *Gale v. IBM Corp.*, 781 N.Y.S.2d 45, 47 (2d Dep't 2004); Ohio: *Butler v. Sterling, Inc.*, No. 98-3223, 2000 WL 353502, at *4-5 (6th Cir. Mar. 31, 2000); Texas: *Texas Carpenters Health Benefit Fund v. Philip Morris Inc.*, 21 F. Supp. 2d 664, 676-78 (E.D. Tex. 1998), *aff'd*, 199 F.3d 788 (5th Cir. 2000).

[16] Indiana, Pennsylvania, Texas, and New York's consumer protection statutes also require that a plaintiff plead and prove reliance on the purported misrepresentation. *See* Ind. Code Ann. § 24-5-0.5-4(a) (West 2008); *Weinberg*, 777 A.2d at 446; *Henry Schein, Inc. v. Stromboe*, 102 S.W.3d 675, 685-86 (Tex. 2002); *Gale*, 781 N.Y.S.2d at 47.

2000); A*MPAT/Midwest, Inc. v. Ill. Tool Works Inc.*, 896 F.2d 1035, 1041 (7th Cir. 1990) ("[F]raud must induce reliance – must in other words be both believed (if it is not believed, it can hardly be described as fraud) and acted on."). The Funds do not identify a single misrepresentation made to them by Pfizer. Instead, they affirmatively plead that the "target populations" of Pfizer's alleged scheme were "pharmacy benefit decision makers, physicians, and consumers," not the Funds. SAC ¶¶ 114-15. The Funds, therefore, do not and cannot allege that they relied or "acted on" statements that they do not even allege they were aware of. *See, e.g., Sec. Investor Prot. Corp.*, 222 F.3d at 71-72 (affirming dismissal of fraud claim because plaintiffs failed to allege they received defendants' alleged misrepresentations).

The Funds seek to avoid this fatal defect by, once again, invoking the fraud-on-the-market theory and alleging that they "relied on Pfizer's misrepresentations . . . by paying excessive prices for [Lipitor]." SAC ¶ 233; *see also id.* ¶¶ 241, 248, 255. Courts in the Funds' states, however, have refused to extend the presumption of reliance supplied by the fraud-on-the-market theory in federal securities cases to common law fraud or negligent misrepresentation claims. *See, e.g., Sec. Investor Prot. Corp.*, 222 F.3d at 73 ("New York has not adopted . . . [the] fraud on the market theory to allow a presumption of reliance in common-law fraud cases . . . ."); *Jacobs v. Osmose, Inc.*, No. 01-944-CIV, 2002 WL 34241682, at *4 (S.D. Fla. Jan. 3, 2002) (to state a fraud claim, "Florida law requires an allegation of actual reliance, not a generalized 'fraud on the market' [claim]") (citation omitted); *Hamilton Partners, Ltd. v. Sunbeam Corp.*, No. 99-cv-8275, 2001 WL 34556527, at *16 (S.D. Fla. July 3, 2001) (same for negligent misrepresentation); *In re First Merchs. Acceptance Corp. Sec. Litig.*, No. 97 C 2715, 1998 WL 781118, at *13 (N.D. Ill. Nov. 4, 1998) ("'Plaintiffs' contention that they should be able to proceed on [Illinois] common law fraud [and negligent misrepresentation] claim[s] based on a

"fraud-on-the-market" theory . . . is . . . without merit.'") (citation omitted).[17]

II. THE FUNDS' CLAIMS ARE PREEMPTED BY THE FDCA

The SAC should also be dismissed as both an impermissible attack on the FDA's approval and continuing oversight of Lipitor and its labeling, and an improper attempt to privately enforce the provisions of the FDCA governing the regulation of off-label marketing. First, the Funds seek to impose on Pfizer, through their RICO and state law claims, disclosure requirements and marketing limitations that are contrary to the FDA-approved Lipitor label. The Funds allege, for example, that there is insufficient clinical evidence to support the use of any statin – including Lipitor – in women or persons over 65 who do not already have heart disease or diabetes (*see* SAC ¶¶ 4, 25, 102-04), and that the FDA-approved Lipitor label "misleadingly omits many and potentially devastating side effects." *Id.* ¶ 100; *see also id.* ¶¶ 82-89, 105, 226, 237-40.[18] On their face, these claims conflict directly with the FDA's repeated findings, in approving Lipitor and its label, that the studies that support its approved indications, warnings, and other prescribing information are "adequate and well controlled," and that the label is not "false or misleading." 21 U.S.C. § 355(d); *see also* 21 C.F.R. § 314.105(c) (2008). As a result, the Funds' claims are plainly preempted because they "conflict with" or would "prevent or frustrate the accomplishment of a federal objective" – the FDA's exclusive authority over drug safety, labeling, and marketing. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000); *see*

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[17] *See also* New Jersey: *Kaufman v. i-Stat Corp.*, 754 A.2d 1188, 1201 (N.J. 2000); Ohio: *In re Donahue Secs, Inc.*, No. 01-1027, 2004 WL 3152763, at *5-6 (Bankr. S.D. Ohio Nov. 23, 2004); Pennsylvania: *Wallace v. Sys. & Comp. Tech. Corp.*, No. CIV. A. 95-CV-6303, 1997 WL 602808, at *23-24 (E.D. Pa. Sept. 23, 1997); Texas: *Gyarmathy & Assocs., Inc. v. Tig Ins. Co.*, No. 3:02-CV-1245, 2003 WL 21339279, at *3 & n.6 (N.D. Tex. June 3, 2003); *cf.* Indiana: *Dryden v. Sun Life Assurance Co. of Can.*, 737 F. Supp. 1058, 1068 (S.D. Ind. 1989) (dismissing fraud claim for failure "to allege the essential element of detrimental reliance"), *aff'd*, 909 F.2d 1486 (7th Cir. 1990).

[18] To the extent the Funds base their claims on challenges to Lipitor's FDA-approved *patient information insert*, rather than the full prescribing information contained in the FDA-approved label (*see* SAC ¶¶ 82-85; *supra* n. 4), those claims are further precluded by the learned intermediary doctrine, under which a manufacturer's duty to warn of risks associated with a prescription drug runs not to patients but to *physicians*. *See, e.g.*, *Ashman v. SK & F Lab Co.*, 702 F. Supp. 1401, 1405 (N.D. Ill. 1988); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007).

also Pa. Employees Benefit Trust Fund v. Zeneca Inc., 499 F.3d 239, 253 (3d Cir. 2007) (affirming dismissal of state consumer fraud claims alleging deceptive advertising of Nexium as "preempted by the extensive federal legislative and regulatory framework" under the FDCA).

The Third Circuit's decision in *Zeneca* is directly on point. The court recognized that "[t]o allow generalized state consumer fraud laws to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives." *Zeneca*, 499 F.3d at 253. It further emphasized that "[a]n even stronger case for preemption occurs when," as in this case, "FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising." *Id.* at 251. As the court explained, "the purpose of protecting prescription drug users in the FDCA would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA." *Id.* Indeed, the *Prohias* court firmly rejected as preempted the same allegations the Funds assert here, which challenge the FDA's approval of Lipitor for the prevention of heart disease in women and the elderly without diagnosed CHD, and the marketing of Lipitor consistent with that approval. *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007) ("[T]he plaintiffs['] efforts to hold Pfizer liable for the advertisements conflicts with the FDA's jurisdiction over drug labeling, and specifically its approval of Lipitor to reduce the risk of heart disease in some patients. Those claims are therefore preempted by federal law."); *see also Colacicco v. Apotex Inc.*, 521 F.3d 253, 271 (3d Cir. 2008) (affirming finding that plaintiffs' failure-to-warn claims involving defendants' antidepressants were "preempted by the FDA's actions [involving the drugs' labeling] taken in accordance with its statutory authority"). These well-reasoned precedents direct the dismissal of all of the Funds' claims that the Lipitor label and Pfizer's advertising

misrepresented Lipitor's safety, efficacy, and approved uses because they conflict directly with the FDA's authority.[19] Many of the consumer protection statutes at issue also exempt conduct that has been approved by a federal agency or is otherwise in compliance with federal law.[20]

The SAC also impermissibly attempts to privately enforce the FDCA and regulations defining and governing the promotion of off-label uses. *See, e.g.*, 21 U.S.C. § 352(n) (defining "misbranding"); *id.* § 360aaa *et seq.* and 21 C.F.R. § 99.1 *et seq.* (establishing requirements for drug manufacturers' dissemination of information about off-label uses). The right to enforce these laws belongs exclusively to the federal government.[21] *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."); *see also Buckman*, 531 U.S. at 349 n.4 (section 337(a) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA]"); *accord Zeneca*, 499 F.3d at 253.[22] The Funds' suit falls squarely within this prohibition against private actions. Their price inflation theory of injury is

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[19] Pfizer strongly maintains that the Funds' claims are barred as a matter of law. However, should the Court determine that there is any justiciable claim, it would be appropriate to stay this action, under the doctrine of primary jurisdiction, so that the FDA can address, in the first instance, the regulatory issues that are central to each of the Fund's claims. *See Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 654 (1973) ("Threshold questions within [the FDA's] peculiar expertise . . . are appropriately routed to the agency, while the court stays its hand."); *accord Bernhardt v. Pfizer Inc.*, No. 00 Civ. 4042, 2000 WL 1738645, at *3 (S.D.N.Y. Nov. 22, 2000).

[20] *See, e.g., Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 942 (7th Cir. 2001) (rejecting ICFA challenge to promotion of prescription drug); *Prohias*, 490 F. Supp. 2d at 1233-35 (Florida statute barred challenges to advertising consistent with Lipitor label); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144-45 (S.D.N.Y. 1987) (dismissing N.Y. Gen. Bus. Law § 349 claim based on FDA-approved label); *see also* Ind. Code Ann. § 24-5-0.5-6 (West 2008) (statute "does not apply to an act . . . required or expressly permitted by federal law"); Ohio Rev. Code Ann. § 1345.12(A) (West 2006) (same).

[21] Notably, although the FDCA does not provide a private right of action, it does permit individuals to petition the FDA to take action. *See* 21 C.F.R. §§ 10.25, 10.30 (2008); *Buckman*, 531 U.S. at 348 (under section 10.30, "citizens may report wrongdoing and petition the [FDA] to take action"); *see also Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d at 178 (noting that plaintiffs who lacked standing to bring consumer action could "avail themselves of [the administrative] forum"). The Funds neither acknowledge nor allege that they have pursued this procedure.

[22] It is also well established that plaintiffs cannot use a civil RICO suit to bootstrap a private right of action onto an administrative statute, like the FDCA, that otherwise does not provide for one. *See, e.g., Norman v. Niagara Mohawk Power Corp.*, 873 F.2d 634, 637-38 (2d Cir. 1989); *Ayres v. GM Corp.*, 234 F.3d 514, 521-22 (11th Cir. 2000); *Danielsen v. Burnside-Ott Aviation Training Ctr., Inc.*, 941 F.2d 1220, 1228-29 (D.C. Cir. 1991).

predicated on alleged violations of the FDCA and FDA off-label marketing regulations,[23] and the Funds plainly seek a remedy – a determination of and penalties for off-label marketing – that Congress has committed exclusively to the FDA. Indeed, federal courts have consistently foreclosed claims, regardless of legal theory, that a manufacturer or distributor has unlawfully promoted a product for a use for which it has not been approved by the FDA. *See PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (action challenging advertising of diet product that plaintiff alleged was being "sold without proper FDA approval" was an improper attempt "to privately enforce alleged violations of the FDCA").[24]

III. THE FUNDS' CLAIMS ARE PREEMPTED BY ERISA

All of the state law claims of at least nine of the Funds are preempted by the Employee Retirement Income Security Act ("ERISA") both because they conflict with the exclusive enforcement regime under ERISA and because adjudication of their claims would require the Court to interpret and apply the terms of employee benefit plans.[25] "ERISA preempts state laws that 'relate to' employee benefits plans." *Metropolitan Life Ins. Co. v. Bigelow*, 283 F.3d 436,

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[23] *See, e.g.*, SAC ¶ 2 ("The claims against Pfizer ***arise from*** (1) the Company's . . . illegal and misleading marketing tactics, which included the 'off-label' promotion of Lipitor for uses that are contrary to the drug's [FDA] approved uses.") (emphasis added); *id.* ¶ 3 ("A primary component of Pfizer's illegal scheme has been its efforts to expand the market for Lipitor by promoting the off-label use of the drug."); *id.* ¶ 38 ("[A]ny marketing of Lipitor that does not conform with the guidelines set forth in ATP III is considered off-label marketing ***and violates FDA regulations***.") (emphasis added); *see also id.* ¶¶ 31-36, 108-47, 211, 221-24, 230-35, 244-50.

[24] *See also Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (affirming dismissal of false advertising claim on same ground); *Autin v. Solvay Pharm., Inc.*, No. 05-2213, 2006 WL 889423, at *4-5 (W.D. Tenn. Mar. 31, 2006) (dismissing on same grounds tort and consumer protection claims based on allegations that defendant marketed an unapproved drug); *Anthony v. Country Life Mfg., L.L.C.*, No. 02 C 1601, 2002 WL 31269621, at *1 (N.D. Ill. Oct. 9, 2002) (dismissing ICFA claim where allegations "amount[ed] to nothing other than an attempt to enforce the FDCA"), *aff'd*, 70 F. App'x 379 (7th Cir. 2003); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306, 316-17 (C.D. Cal. 1996) (dismissing Lanham Act and consumer protection claims that would "'usurp[] the FDA's discretionary role in the application and interpretation of its regulations'") (citation omitted).

[25] Because the Funds provide medical benefits to members pursuant to healthcare plans that were established or maintained by one or more employer or employee organizations, *see* SAC ¶¶ 8-14 & 16-17, the Funds are subject to ERISA. *See* 29 U.S.C. § 1002(1). To the extent that two Plaintiffs – Fire & Police Retiree Health Care Fund, San Antonio and the NYC Sergeants Fund – might qualify as "government plans" under ERISA, their state law claims would not be subject to ERISA preemption. *See* 29 U.S.C. § 1003(b)(1) (exempting government plans).

440 (2d Cir. 2002) (quoting 29 U.S.C. § 1144(a)). "The Supreme Court has held that 'a state law relates to an ERISA plan if it has a connection with or reference to such a plan." *Id.* (quoting *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 147 (2001)). In particular, any state law claim, the adjudication of which "necessarily involves interpretation of the contract itself . . . falls within the ERISA preemption provision." *Toussaint v. JJ Weiser & Co.*, No. 04 Civ. 2592(MBM), 2005 WL 356834, at *16 (S.D.N.Y. Feb. 13, 2005). Here, the Funds' state law claims could not be adjudicated without interpretation and application of, at a minimum, the "medically necessary" or "medical necessity" terms of the Funds' benefit plans: Each Fund alleges that it "covers the cost of health care for eligible participants . . . including paying for *medically necessary* uses of drugs," and that Pfizer "caused Lipitor to be prescribed to persons for whom the drug is *not medically necessary*." SAC ¶¶ 8-14, 16-17, & 110 (emphases added). Courts have consistently found similar claims preempted. For instance, in *Davis v. SmithKline Beecham Clinical Laboratories*, 993 F. Supp. 897 (E.D. Pa. 1998), plaintiffs sought to recoup money that ERISA plans had allegedly paid to defendant for laboratory testing where the ERISA plans allowed "payment only for 'medically necessary' tests." *Id.* at 899. The court held that all of plaintiffs' state law claims were preempted because they could not be adjudicated without "examination and interpretation" of the ERISA plans. *Id.*[26] The same result is warranted here.

IV. THE FUNDS' CLAIMS UNDER SEVERAL CONSUMER PROTECTION STATUTES FAIL FOR ADDITIONAL STATUTE-SPECIFIC REASONS

As set forth below, the Funds' claims under the Ohio Consumer Sales Practices Act ("OCSPA"), Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), the Indiana Deceptive Consumer Sales Act ("DCSA"), the Texas Deceptive Trade Practices and

[26] *See also Cent. States, Se. & Sw. Areas Health & Welfare Fund v. Neurobehavioral Assocs., P.A.*, 53 F.3d 172, 174 (7th Cir. 1995) (state law claims to recover payments to medical provider were "preempted by ERISA").

Consumer Protection Act ("DTPA"), the New Jersey Consumer Fraud Act ("NJCFA"), and New York General Business Law §§ 349 & 350 ("NYGBL §§ 349 & 350") are each deficient for additional, and independently dispositive, statute-specific reasons.[27]

A. The Ohio Fund Is Not a "Consumer" Who Engaged in a "Consumer Transaction" and Its Class Action Allegations Do Not Meet the Requirements of the OCSPA

The Ohio Fund has no standing under the OCSPA because the Fund is not a "consumer" who engaged in a "consumer transaction," as required by the statute. *See* Ohio Rev. Code Ann. § 1345.01(A), (D) (West 2006). Indeed, the Ohio Fund *cannot* be such a consumer under Ohio's statute because it is not a *natural person*. *See City of Findlay v. Hotels.com, L.P.*, 441 F. Supp. 2d 855, 862 (N.D. Ohio 2006) ("[T]he OCSPA 'requires that a consumer be an "individual,"' and '[t]he term "individual" has been interpreted to mean a natural person.'") (citation omitted); *accord Culbreath v. Golding Enters., L.L.C.*, 872 N.E.2d 284, 290 (Ohio 2007). The Ohio Fund's claim is also barred because it does not and cannot allege that *it* engaged in a "consumer transaction" with Pfizer: any purchase or transfer of Lipitor (and none is identified) was by or to a Fund member, not the Fund. *See Riley v. Supervalu Holdings, Inc.*, No. C-040668, 2005 WL 3557395, at *3 (Ohio Ct. App. Dec. 30, 2005) ("For a transfer of goods to qualify as a 'consumer transaction' under the OCSPA, *the transfer must be 'to the individual*.'") (emphasis added).

[27] This Court should also dismiss with prejudice the Funds' RICO and state law consumer protection act claims to the extent they fall outside the applicable statutes of limitations. *See Jenkins v. Arcade Bldg. Maint.*, 44 F. Supp. 2d 524, 531 (S.D.N.Y. 1999). Although the Funds seek relief for alleged injuries occurring "between January 1, 2002, through the present," *see* SAC at 1, that period extends beyond the statutes of limitations for their RICO and consumer protection act claims. Those are: two years for the Indiana, Ohio, and Texas claims, *see A.J.'s Auto. Sales, Inc. v. Freet*, 725 N.E.2d 955, 964-65 (Ind. Ct. App. 2000); *Zaremba v. Marvin Lumber & Cedar Co.*, 458 F. Supp. 2d 545, 552 (N.D. Ohio 2006); *Grant-Brooks v. WMC Mortgage Corp.*, No. 3:02-CV-2455, 2003 WL 23119157, at *7 (N.D. Tex. Dec. 9, 2003); and three years for the Illinois and New York claims, *see Lantz v. Am. Honda Motor Co.*, No. 06 C 5932, 2007 WL 1424614, at *7 (N.D. Ill. May 14, 2007); *Soskel v. Handler*, 736 N.Y.S.2d 853, 854-56 (Sup. Ct. 2001). Because the Florida, New Jersey, and Pennsylvania acts do not provide a statute of limitations, the Illinois limitations period of three years also governs those claims. *See Auscape Int'l v. Nat'l Geographic Soc'y*, 461 F. Supp. 2d 174, 181-82 (S.D.N.Y. 2006) ("If a case is transferred pursuant to 28 U.S.C. § 1404(a) . . . the [substantive state] law of the transferor court applies."). The RICO claims are subject to a four-year limitation. *See Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156-57 (1987).

In addition, the Ohio Fund's class action demand must be dismissed because it has not complied with the statute's express requirement that a plaintiff bringing a claim as a class action allege a *prior* determination by an Ohio state court or the Ohio Attorney General that the specific conduct complained of is "unfair or deceptive" under the Act. *See* Ohio Rev. Code Ann. § 1345.09(B) (West 2006); *see also Marrone v. Philip Morris USA, Inc.*, 850 N.E.2d 31, 38 (Ohio 2006). The Ohio Fund has not alleged, and cannot identify, any prior determination that would satisfy this requirement. *See City of Findlay*, 441 F. Supp. 2d at 863 (dismissing class action claim for failure to plead prior determination); *Johnson v. Microsoft Corp.*, 802 N.E.2d 712, 720-21 (Ohio Ct. App. 2003) (affirming dismissal for same), *aff'd*, 834 N.E.2d 791 (Ohio 2005).

B. The Ohio, Pennsylvania, and Indiana Funds Did Not "Purchase" Lipitor for Personal, Family, or Household Purposes

The Ohio Fund's claim suffers from another fatal defect, which also bars the claims of the Pennsylvania and Indiana Funds: Any "purchase" by the Funds (and none is alleged) would *not* have been for "purposes that are primarily personal, family, or household," as required by the relevant statutes. Ohio Rev. Code Ann. § 1345.01(A) (West 2006); *see also* 73 Pa. Stat. Ann. § 201-9.2(a) (West 1993 & Supp. 2008) (purchase must be "primarily for personal, family or household purposes"); Ind. Code Ann. §§ 24-5-0.5-3(a) & 24-5-0.5-2(a)(1) (West 2008) (alleged violations must involve "a sale . . . to a person for purposes that are primarily personal, familial . . . or household"); *Ferron v. Zoomego, Inc.*, No. 07-4007, 2008 WL 1988587, at *3 (6th Cir. May 7, 2008) (affirming dismissal for failure to allege that transaction was "'for purposes that are primarily personal, family, or household'"); *Weinberg*, 777 A.2d at 446 (Pennsylvania statute required that plaintiff allege a purchase for its *own* "personal or household purposes as opposed to business purposes"). Here, the Funds allege that they are "trust fund[s]" in the business of "cover[ing] the cost of healthcare for eligible participants, including paying for

medically necessary uses of drugs." SAC ¶¶ 13, 14, 16-17. Thus, any "purchase" of Lipitor was made in furtherance of their business purpose and cannot support a private cause of action under the OCSPA, Pennsylvania's UTPCPL, or the Indiana DCSA, as a matter of law. *See Culbreath*, 872 N.E.2d at 290 ("Consumer transactions are expressly restricted to transactions 'for purposes that are primarily *personal, family, or household*.' . . . None of these purposes apply to a business."); *see also Balderston v. Medtronic Sofamor Danek, Inc.*, 285 F.3d 238, 242 (3d Cir. 2002) (affirming dismissal of surgeon's Pennsylvania UTPCPL claims against a bone screw manufacturer because surgeon purchased screws for use in patients, not for his personal use).[28]

C. The Texas Fund Does Not Have Standing Under the DTPA

The Texas Fund's DTPA claim must be dismissed for several independently dispositive reasons. First, the Texas Fund does not have standing under the Texas DTPA because that statute limits claims to "'consumer[s]'" who "seek[] or acquire[] by purchase or lease, any goods or services." Tex. Bus. & Com. Code Ann. § 17.45(4) (Vernon 2002). Under Texas law, the Texas Fund did not "seek" or "acquire" Lipitor; it was merely "the ultimate source of payment" for Lipitor prescribed for its beneficiaries, SAC ¶ 218. *See Hernandez v. Kasco Ventures, Inc.*, 832 S.W.2d 629, 634 (Tex. Ct. App. 1992) (plaintiff who "never owned the [products]" could not recover under DTPA); *see also Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 327-328 (5th Cir. 2002) (dismissing DTPA claim where plaintiff did not allege

[28] In addition, the Pennsylvania Funds did not even "purchase" Lipitor within the meaning of the UTPCPL. *See* 73 Pa. Stat. Ann. § 201-9.2(a) (West 1993 & Supp. 2008) (standing limited to person who "purchases or leases goods or services"). The Funds admit that they are only "third party payors," *see, e.g.*, SAC ¶ 220, and allege only that they were "the ultimate source of payment" for Lipitor prescribed for their beneficiaries. *Id.* ¶ 218. But "[p]aying for part of the cost of something is not the same as buying it." *In re Rezulin Prods. Liab. Litig.*, 390 F. Supp. 2d 319, 333 (S.D.N.Y. 2005). In *Rezulin*, the court held that the mere fact that an HBP alleged that it had "paid most of the cost of the drug" prescribed to its members did not make it a purchaser, i.e., "'[o]ne who *obtains* property for money or other valuable consideration; a buyer.'" *Id.* at 332 (citation omitted); *accord Gottlieb v. Tropicana Hotel & Casino*, 109 F. Supp. 2d 324, 331-332 (E.D. Pa. 2000) (defining "purchase" in same terms under UTPCPL). The Pennsylvania Funds did not "obtain" Lipitor and thus have no standing under the statute.

that it sought or acquired goods). Second, "'goods' and 'services,' as defined under the DTPA, must be 'purchased or leased *for use' by the party seeking to state a cause of action*." *Crown Life Ins. Co. v. Casteel*, 22 S.W.3d 378, 386 (Tex. 2000) (citation omitted) (emphasis added). Even assuming *arguendo* that the Texas Fund actually "purchased" Lipitor, it does not and cannot allege that it purchased the drug for its own use. Third, the "Texas Supreme Court has found the defendant's deceptive trade act or practice is not actionable under the DTPA unless it was committed in connection with the plaintiff's transaction in goods and services." *Dagley v. Haag Eng'g Co.*, 18 S.W.3d 787, 792 (Tex. Ct. App. 2000) (citing *Amstadt v. U.S. Brass Corp.*, 919 S.W.2d 644, 650 (Tex. 1996)). This requirement is not met where, as here, "none of [the defendant's] alleged misrepresentations were directly communicated to [the plaintiff]." *Id.*

D. The New Jersey and New York Funds' Consumer Protection Claims Fail

The claims under the NJCFA and NYGBL §§ 349 & 350 are similarly deficient. The NJCFA claim fails because the New Jersey Fund, Welfare Fund of Teamsters Local Union 863 ("Local 863"), is not a "consumer." "It is well-settled law that one must be a 'consumer' in order to sue under [the NJCFA's private remedy provision]." *Conte Bros. Auto., Inc. v. Quaker State-Slick 50, Inc.*, 992 F. Supp. 709, 716 (D.N.J. 1998), *aff'd*, 165 F.3d 221 (3d Cir. 1998). To be a "consumer" for purposes of the NJCFA, the plaintiff must actually use the items purchased, or, in the words of the appellate division, a consumer is one who "'diminishes or destroys [the] utilit[y]'" of the purchased product. *Windsor Card Shops Inc. v. Hallmark Cards, Inc.*, 957 F. Supp. 562, 567 n.6 (D.N.J. 1997) (citation omitted); *accord E. Coast Office Sys., Inc. v. Citicorp Vendor Fin., Inc.*, No. 06-24, 2006 WL 3257091, at *3 (D.N.J. Nov. 9, 2006).

Local 863 is clearly not a "consumer" under this definition. Even if the Fund had pleaded that it purchased Lipitor (which it did not), it is the *member* – and not Local 863 – that

would have taken – and "diminished or destroyed the utility" of – Lipitor. Indeed, in *Rezulin*, Judge Kaplan dismissed a NJCFA claim brought by an HBP for this exact reason. *See* 390 F. Supp. 2d at 340 (granting summary judgment). The court explained that under New Jersey law, "the plaintiff must in some sense be the one who benefits from the use of the good[s]." *Id.* The New Jersey Fund here – like the HBP in *Rezulin* – "[is] no such thing." *Id.* Similarly, the NYGBL §§ 349 & 350 claims must be dismissed because where, as here, "'the gravamen of the complaint is harm to a business as opposed to the public at large, the business does not have a cognizable cause of action.'" *Vitolo v. Mentor H/S, Inc.*, 426 F. Supp. 2d 28, 34 (E.D.N.Y. 2006) (citation omitted), *aff'd*, 213 F. App'x 16 (2d Cir. 2007).[29]

V. THE FUNDS' NEGLIGENT MISREPRESENTATION CLAIMS FAIL FOR SEVERAL ADDITIONAL REASONS

The Funds' negligent misrepresentation claims fail for several additional reasons. First, the Indiana claim is barred because that state does not recognize the tort of negligent misrepresentation "outside the context of employment relationships." *Ball v. Versar, Inc.*, No. IP01-0531-C, 2002 WL 31045357, at *5 (S.D. Ind. Sept. 6, 2002). Second, the Illinois Funds' claims fail because the SAC alleges a purely economic loss. *See Moorman Mfg. Co. v. Nat'l Tank Co.*, 435 N.E.2d 443, 453 (Ill. 1982) (plaintiffs "cannot recover for solely economic loss under the tort theories of . . . negligence and innocent misrepresentation").[30] Third, the New York and Ohio Funds' claims are deficient because the Funds do not and cannot identify *any* relationship with Pfizer, much less the type of special business relationship to which these states

[29] *Accord Global Entm't, Inc. v. N.Y. Tel. Co.*, No. 00 Civ. 2959, 2000 WL 1672327, at *7 (S.D.N.Y. Nov. 6, 2000) (Stein, J.). The same "consumer oriented" requirement applies to claims under NY GBL § 350. *See, e.g.*, *Leider v. Ralfe*, 387 F. Supp. 2d 283, 292 (S.D.N.Y. 2005).

[30] Illinois' narrow exception for defendants in the business of supplying information (e.g., lawyers or accountants), does not apply to manufacturers, like Pfizer, that make "tangible noninformational goods." *Orix Credit Alliance, Inc. v. Taylor Mach. Works, Inc.*, 125 F.3d 468, 475 (7th Cir. 1997).

limit negligent misrepresentation claims. *See Tuosto v. Philip Morris USA Inc.*, No. 05 Civ. 9384, 2007 U.S. Dist. LEXIS 61669, at *44-45 (S.D.N.Y. Aug. 21, 2007) (negligent misrepresentation requires either "'actual privity of contract between the parties or a relationship so close as to approach that of privity'") (citations omitted); *Doe v. SexSearch.com*, 502 F. Supp. 2d 719, 731 (N.D. Ohio 2007) (explaining that the requisite "'"special relationship" does not exist in ordinary business transactions'") (citation omitted).[31]

VI. THE FUNDS' UNJUST ENRICHMENT CLAIMS FAIL

Because the Funds' underlying tort claims are insufficient as a matter of law, there is "no justification for permitting plaintiffs to proceed on their unjust enrichment claim once . . . the traditional tort claims" have been dismissed. *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 937 (3d Cir. 1999); *accord Alliance Acceptance Co. v. Yale Ins. Agency, Inc.*, 648 N.E.2d 971, 977 (Ill. App. Ct. 1995) ("'The term "unjust enrichment" is not descriptive of conduct that, standing alone, will justify an action for recovery.'") (citation omitted). In fact, courts faced with assertions of unjust enrichment similar to those presented here have consistently refused to expand this quasi-contractual principle to provide recovery for claims (like the Funds') that are no more than deficient tort claims. *See, e.g.*, *Bober*, 246 F.3d at 943 (affirming dismissal of unjust enrichment claim where complaint did not state claim under the ICFA). The Funds' unjust enrichment claims are also defective because the Funds have not alleged that Lipitor did not lower their members' cholesterol. *See Prohias*, 490 F. Supp. 2d at 1236 (dismissing nearly identical unjust enrichment claim, holding: "[T]he [Fund] paid for a cholesterol-reducing drug for its beneficiaries, and its beneficiaries . . . received the benefit of

[31] The SAC also includes a count for "conspiracy." However, "[w]here, as here, the plaintiffs have pled no underlying substantive claim, a conspiracy count fails as a matter of law." *Int'l Bhd. of Teamsters Local 734 Health & Welfare Trust Fund v. Philip Morris, Inc.*, 34 F. Supp. 2d 656, 665 (N.D. Ill. 1998), *aff'd*, 196 F.3d 818 (7th Cir. 1999); *accord Kirch v. Liberty Media Corp.*, 449 F.3d 388, 401 (2d Cir. 2006).

reduced cholesterol. Under these circumstances, it is not inequitable for Pfizer to retain the price of Lipitor paid by the [Fund].").[32]

CONCLUSION

For all of the foregoing reasons, the Second Amended Complaint should be dismissed in its entirety, with prejudice.

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Respectfully submitted,

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[32] Moreover, the unjust enrichment claims advanced by the New Jersey, New York, and Ohio Funds are deficient for the additional dispositive reason that the Funds do not and cannot allege that they engaged in any transactions in which they conferred a benefit directly upon Pfizer, rather than upon third parties (such as the pharmacies or beneficiaries to whom they made payments or reimbursement for Lipitor). *See, e.g.*, *Rezulin*, 390 F. Supp. 2d at 342 (dismissing unjust enrichment claim by HBP against drug manufacturer under New Jersey law because "[t]he benefit at issue must have been conferred on the defendant by the plaintiff, not by some third party"); *Reading Int'l, Inc. v. Oaktree Capital Mgmt. LLC*, 317 F. Supp. 2d 301, 334 (S.D.N.Y. 2003) ("'[A]n unjust enrichment claim . . . requires some type of direct dealing or actual, substantive relationship with a defendant.'") (citation omitted); *accord Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 799 (Ohio 2005).